Remarks

Claims 1 and 49 have been amended.

The amendment to claim 1 deletes subject matter directed to a non-elected invention (*i.e.*, where z = 1 and X = CH_2). Applicants reserve the right to pursue the deleted subject matter of claim 1 in a divisional application. Claims 1 and 49 have also been amended to more clearly recite the invention. In addition, claim 49 has been amended to correct a typographical error.

1. **Claim Objections**

A. Claims 1-19

Claims 1-19 are objected to for being drawn, in part, to a non-elected invention.

Applicants have amended independent claim 1 to delete the options where z = 1 and X = CH_2. In view of these amendments, Applicants believe that the Examiner's objection has been addressed and request that this objection be withdrawn.

B. Claim 49

Claim 49 is objected to because of the recited phrase "of any of any of."

Claim 49 has been amended to correct this typographical error. Accordingly, Applicants request that this objection be withdrawn.

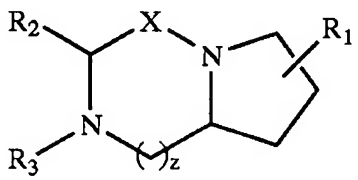
2. **Rejection under 35 U.S.C. § 112, first paragraph**

Claims 1-49 are rejected because the Examiner asserts that the specification, while being enabling for a compound, does not reasonably provide enablement for a "pharmaceutical" thereof. For support of this assertion, the Examiner provides an analysis under *In re Wands*.

Applicants submit that in asserting this rejection, the Examiner has apparently misread the claims. Claims 1-48 are compound claims that simply include pharmaceutically acceptable salts of said compounds. Exemplary pharmaceutically acceptable salts are described in Applicants' specification at *inter alia*, paragraph [0118]. Applicants submit that a person of ordinary skill in this art would also be well aware of typical pharmaceutically acceptable salts such that individually identified salts would not require explicit description in the specification.

Claim 49 recites a composition comprising any of Applicants' claimed compounds in combination with a pharmaceutically acceptable carrier. Similar to the arguments submitted above regarding pharmaceutically acceptable salts, Applicants submit that exemplary pharmaceutically acceptable carriers are fully described in Applicants' specification, in particular at, *inter alia*, paragraph [0117]. Applicants submit that a person of ordinary skill in this art would also be well aware of typical pharmaceutically acceptable carriers such that individually identified carriers would not require explicit description in the specification.

Although Applicants believe that the above comments are adequate to overcome this rejection by the Examiner, Applicants nevertheless will briefly address the Examiner's enablement analysis under *In re Wands*. First, regarding factor 1 (breadth of the claims), Applicants point out that the independent claims 1, 20 and 39 recite sufficient structural features to create the distinct and narrowly tailored group of compounds encompassed by formula (I) as depicted below:



(I)

wherein z = 0 and X = C=O. Such a rather narrow claim scope translates in increased predictability of therapeutic activity of the claimed compounds.

Regarding *In re Wands* factors 3 and 5 (state of the prior art and the level of predictability in the art), the Examiner quotes the previously submitted IDS reference of Hadley as stating that "the success of any promising new therapeutic entity depends, in large part on the development of a suitable delivery system (*i.e.*, the route of administration and dosage form)." It appears that the Examiner is interpreting this passage as indicating that any given melanogenic drug will not be effective unless a novel and unobvious drug delivery system is developed for that particular drug. If that is the Examiner's assertion, Applicants submit that it is (i) unsupported by any technical data, (ii) ignores the key phrase "in a large part" as used by Hadley and (iii) interprets the term "success" in an unrealistic manner. Regarding point (ii), Applicants submit that it is

clear from the quoted passage from Hadley that the authors acknowledge that the development of a suitable drug delivery system is not essential to the success of a new melanogenic drug. Regarding point (iii), Applicants submit that the Examiner has failed to distinguish between commercial and technical success. As a person of ordinary skill in this art would appreciate, one or more well-known formulations would likely be effective at least to some extent for the vast majority of new chemical entities used in medical indications. In satisfying the enablement requirement (and subject to the duty of disclosure of best mode), it is sufficient that any effective method of treatment, as opposed to the optimal method of treatment, is described.

Finally, in rebutting the Examiner's *In re Wands* factor 8 assertion that Applicants' specification does not provide to one of ordinary skill in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in carrying out the full scope of the claimed methods, Applicants point the Examiner to the following sections of Applicants' specification.

- Example 3 at paragraphs [0170] and [0171] describes a competitive binding assay in which various of the claimed compounds are compared for their ability to inhibit the binding of a particular melanocyte-stimulating hormone to its receptor. Using this assay, the percent inhibition of MC1-R, MC3-R, MC4-R and MC5-R was determined for the specific compounds described in Examples 10 through 56 at paragraphs [0179] through [0294]. As stated in paragraphs [0008]-[0010], compounds that act as either agonists or antagonists of these specific melanocortin receptors are believed to be useful in the regulation of various processes such as inflammation, sexual dysfunction, energy homeostasis and melanin production.
- Example 4 at paragraph [0172] describes the determination of the Ki of certain compounds of the invention by measuring the accumulation of intracellular cAMP in HEK-293 cells expressing MC3-R, MC4-R or MC5-R and in B-16 mouse melanoma cells (containing MC1-R).

- Example 5 at paragraph [0173] describes the determination of the agonist/antagonist status with respect to MC1-R, MC4-R and MC5-R of certain compounds of the invention.
- Example 6 at paragraph [0174] describes the ability of the certain of the claimed compounds to induce penile erection in male rats.
- Examples 7 and 8 at paragraphs [0175] and [0176], respectively, describe the change in food intake and body weight of male Sprague-Dawley rats upon administration with certain of the claimed compounds.

Clearly, the above-mentioned sections of Applicants' specification demonstrate the link between the experimentally determined inhibitions of the identified MC receptors by the claimed compounds and the treatment of disease. Accordingly, Applicants respectfully request that this rejection be withdrawn.

3. Rejection under 35 U.S.C. § 112, second paragraph

Claim 49 is rejected as indefinite for allegedly being a dependent claim that does not reference another claim. Further, claim 49 is rejected as allegedly being an omnibus claim that fails to point out what is included or excluded by the claim language.

Applicants have amended claim 49 to depend from any one of independent claims 1, 20 and 39. Accordingly, Applicants respectfully request that this rejection be withdrawn.

4. Requested Rejoinder of Claims

Method claims 50 to 56 are currently withdrawn as directed to a non-elected invention. In the restriction requirement dated August 31, 2006, the Examiner indicated that if product claims were elected and subsequently found allowable, the withdrawn process claims that depend from or otherwise include all of the features of the allowable product claims would be entered as a matter of right. Applicants believe that in light of the above amendments and remarks, the product claims are in a condition for allowance. Accordingly, Applicants respectfully request that withdrawn method claims 50 to 56 be rejoined.

5. Conclusion

Upon consideration of the foregoing, it will be recognized that Applicants have fully and appropriately responded to all of the Examiner's rejections. Accordingly, the claims are believed to be in proper form in all respects and a favorable action on the merits is respectfully requested. The Examiner is invited to contact the undersigned with any questions or concerns that may prevent this requested allowance.

Except for issues payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Respectfully submitted,
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